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**Pulsed, Non-Thermal, High Frequency Electromagnetic Energy
(Diapulse®) in the Treatment of Grade I and II Ankle Sprains**

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Human subjects participated in these studies after giving their free and informed voluntary consent. The Institutional Review Board at Brooke Army Medical Center reviewed the human subjects protocol and the Commander approved it in accordance with AR 40-38, "Clinical Investigation Program." In conducting these studies, investigators adhered to AR 40-38.

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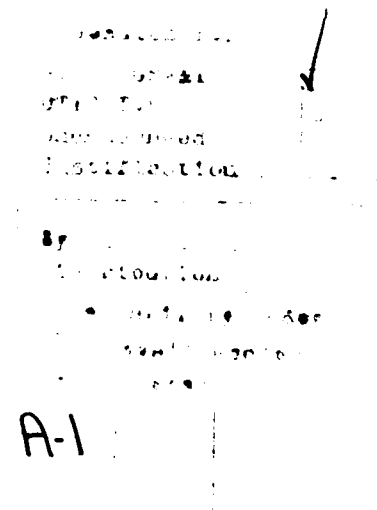
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INTRODUCTION

The use of electromagnetic fields to induce healing began in the late 1800's. At the turn of the century Diathermy units were standard equipment in hospitals, including military field hospitals. Their continuous output of energy caused heating of tissue which may stimulate some healing processes; however, their poorly controlled output created a potential for burns as well.

Pulsed electromagnetic energy was developed in the 1930's by Abraham J. Ginsberg and Arthur Milinowski, who postulated that there were beneficial effects in the application of electrical energy independent of the heat generated. They developed a device that delivered repeated pulses of high energy radio waves of short duration to allow the thermal energy to dissipate and preclude a rise in tissue temperature. The first commercial unit (Diapulse®) was manufactured by Westinghouse prior to World War II. During the war, the Federal Communications Commission (FCC) imposed strict operating frequencies; and it was not until the mid-1950's that a unit could be produced with controlled harmonics to meet FCC regulations (Mr. Jesse Ross, personal communication).

In 1958 the Food and Drug Administration (FDA) permitted Diapulse® to be marketed for human use; and units were used in doctor's offices, clinics, and hospitals. In 1972 the FDA prohibited the use of Diapulse® on humans; however, a Federal court decision reversed this ban in 1987. Because investigators did not have access to Diapulse® for human studies, little research has been done on this treatment modality in the United States in the last twenty years. Double blind studies have been performed at foreign medical centers and published in international journals.

Numerous studies involving animal and human subjects document the efficacy of Diapulse® therapy (Erdman, 1960; Cameron, 1961; Cameron, 1963; Kaplan and Weinstock, 1968; King et al., 1968; Fenn, 1969; Aronofsky, 1971; Wilson, 1972; Wilson,

1974; Goldin, 1981; Barclay et al., 1983; Ionescu and Ionescu, 1984; Raji and Bowden, 1983; Itoh et al., 1991). Most studies involved surgical procedures in which the authors documented accelerated wound healing (Cameron, 1963; Goldin, 1981; Barclay et al., 1983; Raji and Bowden, 1983), increased vascularization (Erdman, 1960; Kaplan and Weinstock, 1968), collagen formation (Cameron, 1961; Raji and Bowden, 1983), and hematoma resolution (Fenn, 1969). In particular, Wilson (1972, 1974) reported that Diapulse® therapy was very beneficial in reducing edema and pain accompanying ankle injuries and decreasing the time to regain full use of the affected joint.

Injuries to the ankle ligaments are very common among individuals in military training. Treatment varies from wrapping the affected area in an elastic bandage to immobilizing the ankle in plaster or surgically repairing torn ligaments after severe injuries. The majority of ankle sprains are minor, but they are accompanied by swelling and pain that may significantly reduce the mobility of a patient for days or weeks.

Because of the impact made by ankle sprains in terms of man-days lost for training, we conducted a prospective, randomized, double-blind study to determine if Diapulse® therapy was effective in altering either swelling or pain associated with acute ankle sprains. Our data show that after a single treatment ankle swelling was reduced 3.5 times that observed in the control (placebo) group. In addition, twice as many subjects from the experimental (treated) group reported a reduction in pain following Diapulse® therapy.

MATERIALS AND METHODS

Fifty patients were enrolled in this study under an approved protocol at Brooke Army Medical Center. Individuals visiting the Orthopaedic Service were asked to participate in this study if they had experienced a Grade I or II ankle sprain within 72 h. Grade I sprains were defined as those in which the ankle ligaments are stretched but not torn and the joint exhibits some swelling but no instability. In the Grade II sprain, the ligaments are partially torn, and the ankle usually swells immediately, possibly with ecchymosis. Patients with Grade III sprains were excluded from this study because this category of sprain involves complete disruption of the ligaments, marked ankle instability, and a possible requirement for corrective surgery.

Each patient was evaluated clinically and radiographically prior to enrollment. Patients were excluded if they were under the age of consent (18 years) or if there was evidence of a fracture, chronic ankle sprain, previous ankle surgery, pregnancy, or cardiac pacemaker.

Volunteers were assigned to one of three groups depending upon when the injury had occurred (<24 h, 24 to 48 h, 48 to 72 h). Within each group, subjects were given sequential numbers and assigned either to the control or to the treatment group using a Monte Carlo technique for randomization. The distribution of individuals in the control group with respect to time of injury was <24 h - 9 subjects, 24 to 48 h - 6 subjects, and 48 to 72 h - 10 subjects. In the experimental group the distribution was <24 h - 10 subjects, 24 to 48 h - 5 subjects, and 48 to 72 h - 10 subjects.

During the study, neither the patient nor the attending physician were aware of the group to which the patient was assigned. The subject was asked to rate the severity of pain on a ten point scale (0 = no pain, 10 = intolerable pain). The physician measured the volumes of both the injured ankle and the unaffected ankle by water displacement. To

quantitate this measurement, a plastic tank was fabricated to accommodate one foot with the water level reaching about 6 inches above the sole. The tank was filled with 3.0 l of water, which brought the level up to the lip of the overflow spout. The patient lowered one foot into the tank until it rested flat on the base, and the physician collected the displaced water in a graduated cylinder.

Subjects were treated by an orthopaedic technician who was aware of patient assignment. Each patient was in the supine position on an examination table with their head elevated on a pillow for comfort. The treatment coil of a Diapulse® unit (Model D-103, Diapulse Corporation of America, Great Neck, NY) was placed over the medial side of the ankle for 30 min, over the lateral side of the ankle for 30 min, and over the epigastric area for 10 min. Placement of the coil over this last area was based upon a report by Erdman (1960) who found that treatment to the epigastric area increased blood flow to the lower extremities.

For the control group, the instrument was kept on "standby" during the treatment time; whereas for the experimental group, the unit was activated with peak power setting of 6 (instrument setting, no units) and frequency of 600 pulses/sec. This provided an output of 120 mW/cm^2 at 27.12 MHz for 65 microseconds followed by a 1665 microsecond pause. Because Diapulse® provokes no sensation, subjects could not determine when the machine was operational or on standby.

Immediately following treatment, the physician repeated the measurement of ankle volume and asked the patient to rate current pain levels while standing. All data were recorded on coded sheets and analyzed independently by a co-investigator. Results are reported as the mean \pm S.D. unless otherwise noted. Comparison between groups was made using the Student's *t*-test (one tail).

RESULTS

For this study, no efforts were made to restrict the age, weight or gender of subjects. Consequently, there was a wide range in ankle displacement volumes. Table I lists the mean values \pm S.D. of ankle displacement volumes for control and experimental groups. The large standard deviations reflect the heterogeneity of the two groups. When data within each group were analyzed using a paired t-test, the results demonstrated significant decreases in displacement volumes following both placebo ($p < 0.05$) and Diapulse® treatment ($p < 0.01$). These results probably reflect the fact that patients were lying prone for over an hour during treatment; and pressure on the affected ankle was reduced.

To determine if there was a difference in the magnitude of change between the control and experimental group, the absolute differences and the percent changes in ankle volume after treatment were calculated. Data in Fig. 1 show that following placebo treatment, subjects experienced an average change in ankle volume of 12 ± 20 cc (range -45 cc to +90 cc) or an average percent change of $1.0 \pm 2.0\%$. The experimental group, however, demonstrated an average change of 44 ± 30 cc (range 9 cc to 111 cc) or an average percent change of $3.4 \pm 2.4\%$ following treatment. Both the absolute volume change and percent change were significantly greater ($p < 0.01$) for the experimental group compared with the control group.

The effects of Diapulse® treatment was also reflected in the individual changes in ankle swelling following treatment. Twelve subjects in the control group demonstrated a percent change in ankle volume of 1.0% or less; and three subjects actually experienced an increase in ankle swelling following placebo treatment. In the experimental group only three subjects demonstrated a reduction of 1.0% or less, and no subjects manifested an increase in swelling.

Elemental analysis of data based upon the elapsed time from injury to treatment was not done because of insufficient numbers of subjects. However, within the experimental group, the data suggest that Diapulse® therapy was effective up to 72 h after injury.

Differences between control and experimental groups were also reflected in the responses of individuals to treatment. When asked to evaluate changes in pain or discomfort, 8 of 24 patients in the control group (one response incomplete) indicated that their pain was reduced after treatment; whereas 16 of 25 patients in the experimental group indicated a reduction in pain. No patients in either group reported feeling worse after treatment. There were no correlations between the amount of swelling and pain or a reduction in swelling and a perceived change in pain in either group.

DISCUSSION

Data presented in this study substantiate the observations of Wilson (1972, 1974): when compared to placebo treatment, Diapulse® effects a greater reduction in edema associated with ankle sprain. Because Wilson reported changes in swelling as a graded score related to linear measurement around the affected ankle, it is not possible to compare our results directly with his. However, in terms of effectiveness, he observed that Diapulse® treatment reduced swelling by more than two times the placebo treatment. In this study, the average reduction in swelling effected by Diapulse® was about 3.5 fold greater than that effected by placebo treatment.

In the subjective area of measuring pain, Wilson reported in both articles that Diapulse® significantly reduced the pain associated with walking on a sprained ankle. In our study, twice as many subjects in the treatment group reported a decrease in the pain experienced with standing on a sprain as compared with the control group, suggesting that treatment induced some analgesic affect. However, we did not observe any correlation between pain and swelling as reported by Wilson, which may be related to different numbers of treatments administered (1 versus 3) and different amount of stress applied to the injured ankle (standing versus walking).

In light of the correlation between our findings and those reported previously, it is reasonable to conclude that a single treatment with Diapulse® significantly reduces edema of Grades I and II sprained ankles. This conclusion, however, raises additional questions which must be addressed in future studies, such as, the course of swelling and the functionality of the limb after treatment and the effectiveness of Diapulse® treatment compared with conventional therapy such as ice or compression wraps.

CONCLUSIONS AND RECOMMENDATIONS

1. On average, a single Diapulse® treatment applied to a sprained ankle (Grade I or II) caused a 3.5 fold greater reduction in edema as compared to a placebo treatment.
2. Additional studies should be undertaken to examine the course of swelling and the functionality of the limb after treatment and the effectiveness of Diapulse® treatment compared with conventional therapy such as ice or compression wraps.
3. In light of other clinical studies, Diapulse® may be an effective method for reducing the edema associated with a variety of traumatic injuries besides sprains.

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ILLUSTRATION

Figure 1. Effect of placebo treatment or Diapulse® treatment on ankle edema resulting from Grade I or II sprains. Open bars represent the average change in the ankle displacement volumes of 25 subjects treated for 70 min with the Diapulse® unit in the standby mode (placebo) or treated for 70 min with the Diapulse® unit operating at a peak power setting of 6 (instrument setting, no units) and a frequency of 600 pulses/sec. Solid bars represent the same data expressed as the average percent change in ankle volumes of the two groups. An asterisk (*) indicates a statistically significant difference ($p < 0.01$) between the Diapulse® treatment and the placebo treatment groups as determined by a t -test (one tail). Error bars reflect one standard deviation.

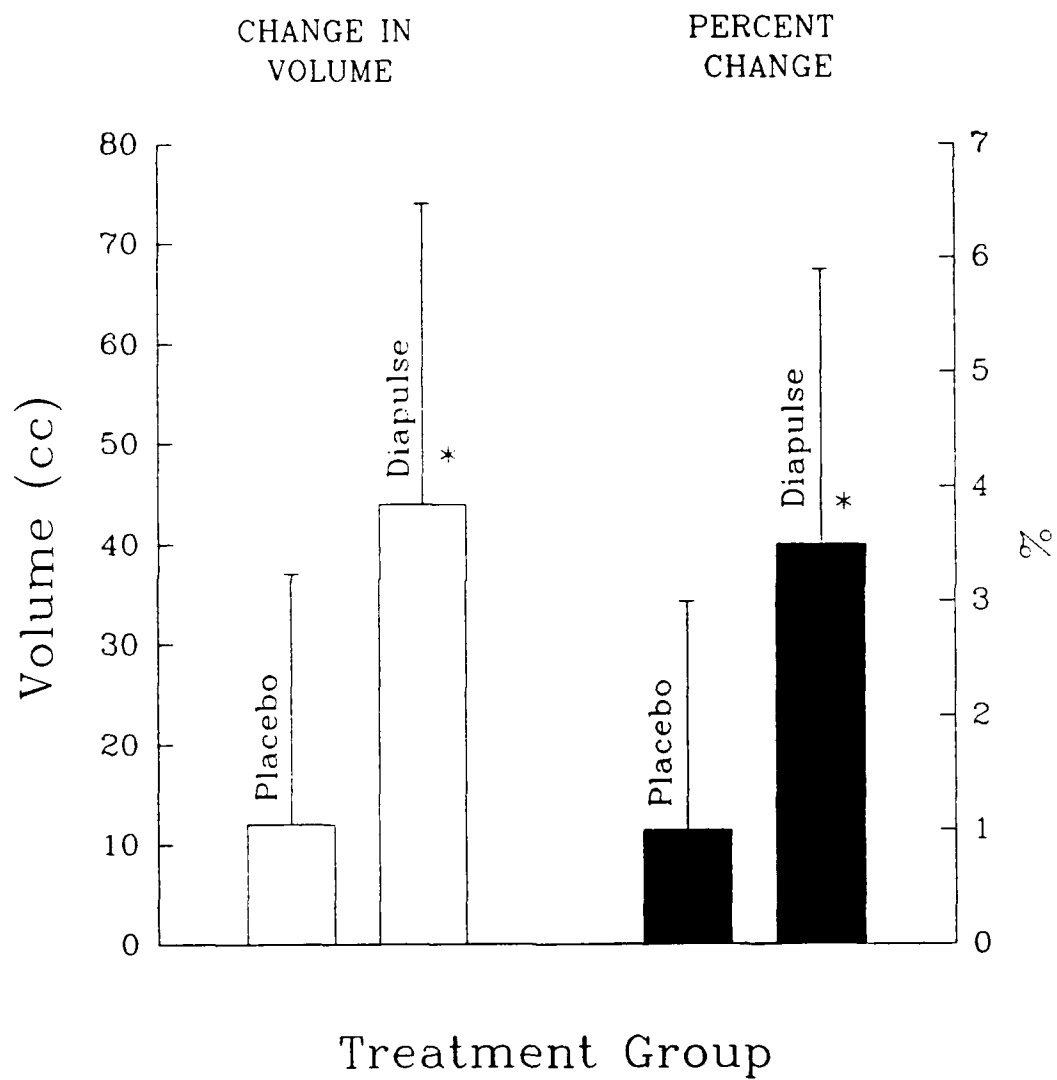


TABLE I. Effect of placebo treatment or Diapulse® treatment on ankle edema resulting from Grade I or Grade II sprains.

MEAN ANKLE DISPLACEMENT VOLUME (cc)			
<u>GROUP</u>	<u>BEFORE</u>	<u>AFTER</u>	<u>DIFFERENCE</u>
Placebo Treatment	1153 ± 216 [*]	1141 ± 213	12
Diapulse® Treatment	1295 ± 257 ^{**}	1251 ± 255	44

^{*} Data represent the mean ankle displacement volume (\pm S.D.) of 25 patients treated for 70 min with the Diapulse® unit in the standby mode. Mean displacement volume after treatment was significantly less ($p < 0.05$) than before treatment as determined by a t -test (paired, one tail).

^{**} Data represent the mean ankle displacement volume (\pm S.D.) of 25 patients treated for 70 min with a Diapulse® unit operating at a peak power setting of 6 (instrument setting, no units) and a frequency of 600 pulses/sec. Mean displacement volume after treatment was significantly less ($p < 0.01$) than before treatment as determined by t -test (paired, one tail).

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